| **Select the appropriate response(s) for the items listed below. Provide comments as necessary.** | **YES** | **NO** | **N/A** |
| --- | --- | --- | --- |
| All participants signed and dated an appropriate IRB approved Informed Consent Document prior to participation in the trial? |  |  |  |
| **Comment:** | | | |
| Have all inclusion and no exclusion criteria been met and documented for each enrolled participant? |  |  |  |
| **Comment:** | | | |
| All withdrawals (e.g., dropouts, lost to follow up) of enrolled participants are documented and reported to the IRB, per their reporting guidlines? |  |  |  |
| **Comment:** | | | |
| Case Report Forms are legible, accurate, complete, and have been verified against adequate and available source documents? Any corrective changes have been made and dated with initials by authorized staff? |  |  |  |
| **Comment:** | | | |
| Is the Delegation of Authority log up to date? |  |  |  |
| **Comment:** | | | |
| Were there any unexpected, serious adverse events related/possibly related to the study device? |  |  |  |
| **Comment:** | | | |
| If there were any unexpected, serious adverse events, were they submitted to both the FDA and IRB within 15 calendar days of notification of the event? |  |  |  |
| **Comment:** | | | |
| Investigational device is properly stored, inventoried, dispensed, and returned? |  |  |  |
| **Comment:** | | | |
| Documented adherence to the protocol, approved amendments, and applicable regulatory requirements, including documentation of all study procedures and assessments? |  |  |  |
| **Comment:** | | | |
| Essential documents and trial records are accurate, complete, updated and are properly maintained according to records retention requirements? |  |  |  |
| **Comment:** | | | |

|  |
| --- |
| **Narrative**  (Include information about when the monitoring was conducted, who performed the monitoring, what data/records were reviewed, and any pertinent findings and follow up actions not included in the comments above) |
|  |

|  |  |  |
| --- | --- | --- |
| **Signatures** | | |
| **Prepared by:** Click or tap here to enter text. | | | |
|  |  |  | |
| **Signature** | **Printed Name** | **Date** | |
|  |  |  | |
| **Reviewed by Principal Investigator:** Click or tap here to enter text. | | | |
|  |  |  | |
| **Principal Investigator Signature** | **Printed Name** | **Date** | |